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PATENT

13579CIPUS

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Wermeling Examiner: To be assigned  
Serial No.: 10/803,521 Group Art Unit: To be assigned  
Filed: March 17, 2004  
For: Intranasal Benzodiazepine Compositions  
Customer No.:

**23719**  
PATENT TRADEMARK OFFICE

Kalow & Springut LLP  
488 Madison Avenue, 19th Floor  
New York, New York 10022

July 7, 2004

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

Sir:

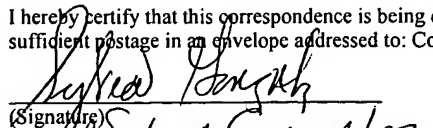
Applicants submit herewith the following disclosure in accordance with the provisions of 37 C.F.R. §§ 1.97 and 1.98.

**I. U.S. PATENT DOCUMENTS**

<b><u>Patent No.</u></b>	<b><u>Date Issued</u></b>	<b><u>Title</u></b>
3,812,853 to Crain	May 28, 1974	Apparatus for applying medication or the like to human nasal passages
4,464,378 to Hussain	August 7, 1984	Method of administering narcotic antagonists and analgesics and novel dosage forms containing same

**Certificate of Mailing Under 37 C.F.R. 1.8**

I hereby certify that this correspondence is being deposited on the date shown below with the United States Postal Service as first class mail with sufficient postage in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

  
(Signature)

Sylvia Gonzalez  
(Printed Name of Person Signing Certificate)

July 7, 2004  
(Date)

**I. U.S. PATENT DOCUMENTS (cont)**

<b><u>Patent No.</u></b>	<b><u>Date Issued</u></b>	<b><u>Title</u></b>
4,673,679 to Aungst, et al	June 16, 1987	Use of prodrugs of 3- hydroxymorphinans to prevent bitter taste upon buccal, nasal or sublingual administration
4,889,860 to Rzeszotarski, et al.	December 26, 1989	Oximes of oxymorphone, naltrexone and naloxone as potent, selective opioid receptor agonists and antagonists
4,973,596 to Cohen	November 27, 1990	Method of administering a narcotic analgesic and dosage forms therefor
4,950,664 to Goldberg	August 21, 1990	Nasal Administration of benzodiazepine hypnotics
4,946,069 to Fuchs 8	August 7, 1990	Dispenser for Manually Discharging Flowable Media
5,132,114 to Stanley, et al	July 21, 1992	Compositions and Methods of Manufacture of Compressed Powder Medicaments
5,169,029 to Behar	December 8, 1992	Mixing dispenser and method of using same
5,225,183 to Purewal, et al.	July 6, 1993	Medicinal aerosol formulations
5,307,953 to Regan	May 3, 1994	Single Dose Dispenser having a Piercing Member
5,397,771 to Bechgaard, et al	March 14, 1995	Pharmaceutical Preparation
5,428,006 to Bechgaard, et al.	June 27, 1995	Method of Administering a Biologically Active Substance

I. U.S. PATENT  
DOCUMENTS  
(cont)

<u>Patent No.</u>	<u>Date Issued</u>	<u>Title</u>
5,529,787 to Merrill, et al.	June 25, 1996	Hydromorphone therapy
5,543,434 to Weg	August 6, 1996	Nasal administration of ketamine to manage pain
5,577,497 to Mecikalski, et al	November 26, 1996	Dry powder inhaler
5,622,166 to Eisele, et al.	April 22, 1997	Dry powder inhaler delivery system
5,629,011 to Illum	May 13, 1997	Composition for nasal administration
5,683,677 to Purewal, et al.	November 4, 1997	Medicinal aerosol formulations
5,693,608 to Bechgaard, et al.	December 2, 1997	Method of administering a biologically active substance.
5,695,743 to Purewal, et al.	December 9, 1997	Medicinal aerosol formulations
5,702,725 to Merrill, et al	December 30, 1997	Hydromorphone therapy
5,766,573 to Purewal, et al.	June 16, 1998	Method of treatment of migraine
5,855,907 to Peyman	January 5, 1999	Method of treatment of migraine
5,866,143 to Elkhoury	February 2, 1999	Topical application of opiod drugs such as morphine for relief of itching and skin disease

I. U.S. PATENT  
DOCUMENTS  
(cont)

<u>Patent No.</u>	<u>Issued Date</u>	<u>Title</u>
5,948,389 to Stein	September 7, 1999	Method of enhancing the analgesic efficacy of locally and topically administered opioids and other local anesthetics.
5,958,379 to Regenold, et al.	September 28, 1999	Pharmaceutical composition
6,015,797 to Camborde, et al.	January 18, 2000	Adenosinergic Agonist Containing Pharmaceutical Composition with Analgesic Activity
6,017,963 to Alfonso, et al	January 25, 2000	Formulation for intranasal administration
RE36,744 to Goldberg	June 20, 2000	Nasal Administration of Benzodiazepine Hypnotics
6,193,984 to Sonne	February 27, 2001	Tocopherol Compositions for Delivery of Biologically Active Agents
6,228,383 to Hansen, et al.	May 8, 2001	Use of Fatty Acid Esters as Bioadhesive
6,255,502 to Penkler, et al.	July 3, 2001	Pharmaceutical Composition Containing Acid Addition Salt of basic drug

6,274,653 to Hecht, et al.	August 14, 2001	Bonding Agent Preparations for Paints, the Production and Use Thereof
6,234,366 to Fuchs	May 22, 2001	Discharge Control for a Media Dispenser
6,610,271 to Wermeling	August 26, 2003	System and method for intranasal administration of lorazepam
6,608,073 to Hussain, et al.	August 19, 2003	Intranasal codeine for the rapid suppression of cough and rapid relief pain
2003/0077300 A1 to Wermeling	April 23, 2003	System and method for intranasal administration of opioids
2003/0163099 A1 to Wermeling et al.	August 28, 2003	Programmable multi-dose intranasal drug delivery device
2003/0206867 A1 to Wermeling	November 6, 2003	System and method for intranasal administration of Lorazepam
2004/0115133 A1 to Wermeling	June 17, 2004	Intranasal Opioid Compositions

## **II. FOREIGN PATENT DOCUMENTS**

<b><u>Publication No.</u></b>	<b><u>Country</u></b>	<b><u>Publication Date</u></b>
WO 90/02737	WO	3/1990

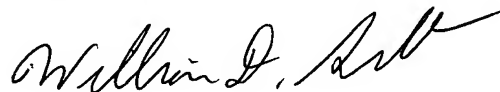
Applicant: Wermeling  
Serial No.: 10/803,521  
Filed: 3/17/2004  
Information Disclosure Statement – Page 6

The items listed above are identified on the accompanying Form PTO 1449. Copies of the foreign patent document items identified above are submitted with this statement.

Applicants take no position on whether any of the items cited above and listed on the accompanying Form PTO 1449 constitute prior art against the subject application under any particular provision of Title 35 of the United States Code.

Because no action has been taken on the merits, Applicants submit that no fee is due at this time. However, if a fee is deemed necessary, please charge Deposit Account No. 11-0171.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "William D. Schmidt", written over a horizontal line.

William D. Schmidt  
Registration No.: 39,492  
Attorney for Applicant

Kalow & Springut LLP  
(212) 813-1600



63273.1

Sheet 1 of 7

Form PTO/SB/08 [modified]  INFORMATION DISCLOSURE STATEMENT BY APPLICANT  (use several sheets if necessary)	Docket No.: <b>13579CIPUS</b>	Application No.: 10/803,521
	Applicants: Wermeling	
	Filing Date: March 17, 2004	Group Art Unit: to be assigned

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL	CITE NO <sup>1</sup>	PUBLICATION NUMBER Number- Kind Code <sup>2</sup> (if known)	PUBLICATION DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT
		3,812,853	05-28-1974	Crain
		4,464,378	08-07-1984	Hussain
		4,673,679	06-16-1987	Aungst, et al.
		4,889,860	12-26-1989	Rzeszotarski, et al.
		4,973,596	11-27-1990	Cohen
		4,950,664	08-21-1990	Goldberg

## FOREIGN PATENT DOCUMENTS

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		WO 90/02737	03-22-1990	Goldberg, Arthur	

## OTHER DOCUMENTS

(including Author, Title, Date, Pertinent Pages, Etc.)


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<p><sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at <a href="http://www.uspto.gov">www.uspto.gov</a> or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.</p> <p>Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.</p> <p>*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>	

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		4,946,069	08-07-1990	Fuchs
		5,132,114	07-21-1992	Stanley, et al.
		5,169,029	12-08-1992	Behar
		5,225,183	07-06-1993	Purewal, et al.
		5,307,953	05-03-1994	Regan
		5,397,771	03-14-1995	Bechgaard

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		5,428,006	06-27-1995	Bechgaard
		5,529,787	06-25-1996	Merrill, et al.
		5,543,434	08-06-1996	Weg
		5,577,497	11-26-1996	Mecikalski, et al.
		5,622,166	04-22-1997	Eisele, et al.
		5,629,011	05-13-1997	Illum

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		5,683,677	11-04-1997	Purewal, et al.
		5,693,608	12-02-1997	Bechgaard
		5,695,743	12-09-1997	Purewal, et al.
		5,702,725	12-30-1997	Merrill, et al.
		5,766,573	06-16-1998	Purewal, et al.
		5,855,907	01-05-1999	Peyman

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		5,866,143	02-02-1999	Elkhoury
		5,948,389	09-07-1999	Stein
		5,958,379	09-28-1999	Regenold
		6,015,797	01-18-2000	Camborde
		6,017,963	01-25-2000	Alfonso, et al.
		RE36,744	06-20-2000	Goldberg

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		6,193,984	02-27-2001	Sonne
		6,228,383	05-08-2001	Hansen, et al.
		6,255,502	07-03-2001	Penkler, et al.
		6,274,653	07-14-2001	Hecht, et al.
		6,234,366	05-22-2001	Fuchs

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		6,610,271	08-26-2003	Wermeling
		6,608,073	08-19-2003	Hussain et al
		2003/0206867 A1	11-06-2003	Wermeling
		2004/0115133 A1	06-17-2004	Wermeling
		2003/0163099 A1	08-28-2003	Wermeling et al.
		2003/0077300 A1	04-24-2003	Wermeling

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